



APW

Docket No. PRD-0007-US-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Andrew Joseph Friedman et al.
Serial No. : 10/626,434 Art Unit:
Filed : July 25, 2003 Examiner: N/A
For : EXTENDED TRANSDERMAL CONTRACEPTIVE REGIMENS

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July 22, 2004
(Date of Deposit)

Joseph S. Kentoffio
(Name of applicant, assignee, or Registered Representative)


(Signature)

July 22, 2004
(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

In addition to the references cited on the attached Form PTO-1449, applicants are aware of a reference to Omtzigt et al published in 1996. Applicants cannot identify a citation for this reference and do not have a copy of the reference. However, it is believed that the reference discloses the results of a study involving 207 women who were administered combination oral contraceptives in a 6 week on and 1 week off cycle. A total of nine such cycles was administered. Half of the women received 30 µg of EE and 75 µg of gestodene daily and the other half received 20 µg of EE and 150 µg of desogestrel daily. For both groups breakthrough bleeding was more frequent in the last 21 days of each cycle, but the EE/gestodene product provided better overall cycle control.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that

these references are available to the Examiner,
copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a) (2) (i)).

☐ There are no listed references which are not in the English language..

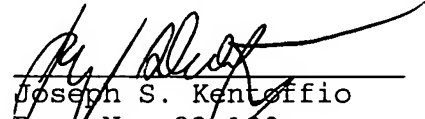
☒ The relevance of those listed references which are not in the English language is as follows: ROUMEN, F.: Pleister en ring: twee nieuwe toedieningsvormen van hormonale combinatieanticonceptie; TFO1 '02 16E JAARGANG, No. 2 p. 32-37; (See English language summary on page 37.)

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to
Deposit Account No. 10-0750/PRD-0007/JSK. This form is
submitted in triplicate.

Respectfully submitted,



Joseph S. Kentoffio
Reg. No. 33,189
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-6586
DATED: July 22, 2004



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
		4,264,575		Zimmerman et al.	04-28-1981	
		4,390,531		Edgren	06-28-1983	
		4,762,717		Crowley, Jr.	08-09-1988	
		5,043,331		Hirvonen et al.	08-27-1991	
		5,098,714	A	Wright et al.	03-24-1992	
		5,108,995	A	Casper	04-28-1992	
		5,208,225	A	Boissonneault et al.	05-04-1993	
		5,211,952	A	Spicer et al.	05-18-1993	
		5,756,490	A	Lachnit et al.	05-26-1998	
		5,770,226	A	Hughes, Jr. et al.	06-23-1998	
		5,876,746	A	Jona et al.	03-02-1999	
		5,898,032	A	Hodgen	04-27-1999	
		5,962,021	A	Hughes, Jr. et al.	10-05-1999	
		5,972,377	A	Jona et al.	10-26-1999	
		5,980,940	A	Spona et al.	11-09-1999	
		6,027,749	A	Schmidt-Gollwitzer et al.	02-22-2000	
		6,071,531	A	Jona et al.	06-06-2000	
		6,077,840	A	Kurihara et al.	06-20-2000	
		6,077,873	A	Loozen	06-20-2000	
		6,110,471	A	Conti et al.	08-29-2000	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. ¹⁶ if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 2 of 7

<i>Application Number</i>	10/626,434
<i>Filing Date</i>	07/24/2003
<i>First Named Inventor</i>	Andrew Joseph Friedman
<i>Group Art Unit</i>	
<i>Examiner Name</i>	N/A
<i>Attorney Docket Number</i>	PRD-0007-US-CIP

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		Number	Kind Code ² (if known)			
		6,139,873	A	Hughes, Jr. et al.	10-31-2000	
		6,177,416	B1	Laurent et al.	01-23-2001	
		6,180,803	B1	Piasco et al.	01-30-2001	
		6,225,297	B1	Stockemann et al.	05-01-2001	
		6,312,722	B1	Schmidt-Gollwitzer et al.	11-06-2001	
		6,313,180	B1	Loozen	11-06-2001	
		6,326,392	B1	Gast et al.	12-04-2001	
		6,340,688	B1	Chwalisz et al.	01-22-2002	
		6,362,237	B1	Chwalisz et al.	03-26-2002	
		6,416,778	B1	Ragavan et al.	07-09-2002	
		6,451,778	B1	Gast	09-17-2002	
		6,451,779	B1	Hesch	09-17-2002	
		6,479,475	B1	Gast	11-12-2002	
		6,500,814	B1	Hesch	12-31-2002	
		6,506,742	B2	Wong et al.	01-14-2003	/
		2001/0027189	A1	Bennink et al.	10-04-2001	
		2002/0035099	A1	Grubb et al.	03-21-2002	
		2002/0061875	A1	Gast et al.	05-23-2002	
		2002/0103179	A1	Wong et al.	08-01-2002	
		2002/0177580	A1	Van Beek et al.	11-28-2002	
		2003/0018018	A1	Hodgen et al.	01-23-2003	

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 7

<i>Application Number</i>	10/626,434
<i>Filing Date</i>	07/24/2003
<i>First Named Inventor</i>	Andrew Joseph Friedman
<i>Group Art Unit</i>	
<i>Examiner Name</i>	N/A
<i>Attorney Docket Number</i>	PRD-0007-US-CIP

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	KindCode ⁵				
		EP	0 911 029	B2	Medical College of Hampton Roads	04-28-1999		
		EP	1 275 394	A2 & A3	Medical College of Hampton Roads	01-15-2003		

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Sheet 4 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		ABRAHAM, S. et al.: Menstruation, menstrual protection and menstrual cycle problems; The Med. J. of Australia, Vol. 142, February 18, 1985, pp. 247-251.	
		AL-AZZAWI F.: Pulsed estrogen therapy: from cellular mode of action to tissue effects; Climacteric 2002 Jun;5 Suppl 2:27-31.	
		ANDERSON, F.D.: The Safety and Efficacy of Seasonale, a Novel 91-Day Extended Oral Contraceptive Regimen; Obstet & Gynecol, April 2002; Vol 99, No. 4 (suppl); p. 26S.	
		CACHRIMANIDOU, A-C et al.: Long-interval treatment regimen with a desogestrel-containing oral contraceptive; Contraception 1993;48, September, pp. 205-216.	
		CACHRIMANIDOU, A-C et al.: Hemostasis profile and lipid metabolism with long-interval use of a desogestrel-containing oral contraceptive; Contraception 1994;50, August, pp. 153-165.	
		CLARKE, A.K. et al.: The Debate Regarding Continuous Use of Oral Contraceptives; The Annals of Pharmacotherapy 2001 November, Vol. 35, pp. 1480-1484.	
		DAVIES, G.C. et al.: Ovarian activity and bleeding patterns during extended continuous use of a combined contraceptive vaginal ring; Contraception 46:269-278, 1992.	
		DE VOOGD, W.S.: Postponement of withdrawal bleeding with a monophasic oral contraceptive containing desogestrel and ethinylestradiol; Contraception August 1991, Vol. 44 No. 2, pp. 107-112.	
		DEN TONKELAAR, I. et al.: Preferred Frequency and Characteristics of Menstrual Bleeding in Relation to Reproductive Status, Oral Contraceptive Use, and Hormone Replacement Therapy Use; Contraception 1999;59, pp. 357-362.	
		FAUSER, B.C.J.M. et al.: Manipulation of Human Ovarian Function: Physiological Concepts and Clinical Consequences; Endocrine Reviews Vol. 18 No. 1, pp.71-106.	
		FINLAY, I.G. et al.: Patterns of contraceptive pill taking in an inner city practice; British Med. J. Vol. 293, 6 September 1986, pp. 599-602.	

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SignatureDate
Considered

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 5 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		FRANKE, H.R. et al.: The effect of continuous combined 17 β -oestradiol and dihydrodydrogesterone on apoptotic cell death and proliferation of human breast cancer cells in vitro; Eur J. Cancer 2002 Nov;38 Suppl 6:S69-70.	
		GLASIER, A.F. et al.: Amenorrhea associated with contraception -- an international study on acceptability; Contraception 67 (2003), pp. 1-8.	
		GUILLEBAUD, J.: The forgotten pill--and the paramount importance of the pill-free week;	
		HAMERLYNCK, J.V.T.H. et al.: Postponement of withdrawal bleeding in women using low-dose combined oral contraceptives; Contraception March 1987 Vol. 35 No. 3, pp. 199-204.	
		KORNAAT, H. et al.: The acceptance of a 7-week cycle with a modern low-dose oral contraceptive (Minulet®); Contraception February 1992 Vol. 45 No. 2, pp. 119-127.	
		KOVACS, G.T. et al.: A trimonthly regimen for oral contraceptives; The British J. of Family Planning 1994, 19, pp. 274-275.	
		KWIECIEN, M. et al.: Bleeding patterns and patient acceptability of standard or continuous dosing regimens of a low-dose oral contraceptive: a randomized trial; Contraception 67 (2003, pp. 9-13.	
		LOUDON, N.B.: Tricycle Pill regime; IPPF Med. Bull., Mar 19:1979, pp. 2-3.	
		LOUDEN, N.B. et al.: Acceptability of an oral contraceptive that reduces the frequency of menstruation: the tri-cycle pill regimen; British Med. J., 1977, 2, pp. 487-490.	
		MARUO, T. et al.: Vaginal rings delivering progesterone and estradiol may be a new method of hormone replacement therapy; Fertil. Steril. 2002, Nov; 78(5), pp. 1010-1016.	
		MARTINEZ-MANAU TOU, J.: Continuous low dose progestagen for contraception; IPPF Med. Bull. 1968;2(5), pp. 2-3.	
		MILLER, L. et al.: Menstrual Reduction With Extended Use of Combination Oral Contraceptive Pills: Randomized Controlled Trial; Obstetrics & Gynecology Vol. 98, No. 5 Part 1, November 2001, pp. 771-778.	

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 6 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		MILLER, L. et al.: Continuous Combination Oral Contraceptive Pills to Eliminate Withdrawal Bleeding: A Randomized Trial; Obstetrics & Gynecology, Vol. 101, No. 4, April 2003, pp. 653-661.	
		MILLER, W.B. et al.: Elimination of the Menses: Psychosocial Aspects; J. Psychiat. Res., 1975, Vol. 12, pp. 153-166.	
		MULDERS, T.M. et al.: Ovarian function with a novel combined contraceptive vaginal ring; Hum. Reprod. 2002 Oct;17(10), pp. 2594-2599.	
		RIZK, D.E.E. et al.: Congenital Afibrinogenemia: Treatment of Excessive Menstrual Bleeding With Continuous Oral Contraceptive; Letters and Correspondence, pp. 237-238.	
		ROUMEN, F.: Pleister en ring: twee nieuwe toedieningsvormen van hormonale combinatieanticonceptie; TFO1 '02 16E JAARGANG, No. 2 pp. 32-37. (see English language Summary on p. 37).	
		RUTTER, W. et al.: Women's attitudes to withdrawal bleeding and their knowledge and beliefs about the oral contraceptive pill; The Medical J. of Australia Vol. 149 October 17, 1988, pp. 417-419.	
		SHORT, R.V.: Why menstruate?; Healthright Vol. 4 No. 4 August 1985, pp. 9-12	
		SUCATO, G. et al.: New options in contraception for adolescents; Curr Womens Health Rep 2001 Oct;1(2), pp. 116-23.	
		SULAK, P.J. et al.: Extending the Duration of Active Oral Contraceptive Pills to Manage Hormone Withdrawal Symptoms; Obstetrics & Gynecology Vol. 89, No. 2 February 1997, pp. 179-182.	
		TUMOLO, J.: Manipulating menstruation. Continuous-use OC regimens a secret no more; Adv Nurse Pract 2002 June;10(6): pp. 85-87.	
		VERCELLINI, P. et al.: Cyproterone acetate versus a continuous monophasic oral contraceptive in the treatment of recurrent pelvic pain after conservative surgery for symptomatic endometriosis; Fertility and Sterility Vol. 77, No. 1, January 2002, pp. 52-61.	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE
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(use as many sheets as necessary)

Sheet 7 of 7

<i>Application Number</i>	10/626,434
<i>Filing Date</i>	07/24/2003
<i>First Named Inventor</i>	Andrew Joseph Friedman
<i>Group Art Unit</i>	
<i>Examiner Name</i>	N/A
<i>Attorney Docket Number</i>	PRD-0007-US-CIP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		VOLLEBREGT, J.A. et al.: A study on postponement of menses with low-dose combined oral contraceptives--Outcome and acceptability; Adv. Contracept 1985; 1, pp. 207.	
		Trial Information from Center Watch Clinical Trials Listing Service.	

Examiner Signature		Date Considered	
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